USER INFORMATION
READ CAREFULLY

HEMACOM LF

CONTINUOUS RENAL REPLACEMENT THERAPY SOLUTION without LACTATE

Sterile and Non-Pyrogenic

Description:
HEMACOM LF is a sterile clear and colourless solution. The solution is used in Continuous Renal Replacement Therapies (CRRT) for hemofiltration, hemodialfiltration and haemodialysis.
HEMACOM LF is packaged in a two compartment bag consist of compartment A and B. The compartment A contains electrolyte and compartment B contains buffer. Both compartments A and B to be mixed before use to obtain the final 5000mL reconstituted solution.

BEFORE RECONSTITUTION			
Compartment A (555mL):		**Compartment B (4445mL):**	
Ingredients	g/L	Ingredients	g/L
Calcium Chloride $2H_2O$ BP	1.98	Sodium Chloride BP	6.18
Magnesium Chloride $6H_2O$ BP	0.91	Sodium Bicarbonate BP	3.59
Sodium Chloride BP	4.21		
Dextrose Anhydrous BP	9.01		

FINAL ELECTROLYTE COMPOSITION (AFTER RECONSTITUTION A + B)		
Electrolytes	**mmol/L**	**mEq/L**
Sodium Ion (Na^+)	140.00	140.00
Calcium Ion (Ca^{++})	1.50	3.00
Magnesium Ion (Mg^{++})	0.50	1.00
Chloride Ion (Cl^-)	109.00	109.00
HCO_3^-	35.00	35.00
Dextrose	5.60	
Calculated Osmolarity		292 mOsm/L

Pharmacodynamics:
HEMACOM LF is pharmacologically inactive. The sodium, calcium, magnesium and chloride ions are present at concentrations similar to physiological levels in plasma. The solution is used to replace water and electrolytes removed during haemofiltration or to serve as a suitable exchange medium for use during haemodiafiltration or continuous haemodialysis. Bicarbonate is used as an alkalising buffer.

Pharmacokinetics:
Not relevant. The active ingredients are pharmacologically inactive and are present at concentrations similar to physiological plasma levels.

Indication:
As substitution solution in continuous haemofiltration and haemodiafiltration and as dialysis solution in continuous haemodialysis for acute renal failure.

Recommended Dosage:
The volume of substitution solution to be administered will depend on the intensity of the treatment performed and on the amount of solution which has to be replaced in order to achieve the target fluid balance. The dose volume is therefore at the discretion of the responsible physician.

Commonly used flow rates for the substitution solution in haemofiltration and haemodiafiltration are:
Adult: 500 - 1500 mL/hour
Children: 15 - 20 mL/kg/hour

Commonly used flow rates for the dialysis solution (dialysate) in continuous haemodialysis are:
Adult: 500 - 2000 mL/hour
Children: 15 - 20 mL/kg/hour
HEMACOM LF, when used as a substitution solution is administered into the circuit before (predilution) or after the haemofilter (post-dilution).

Route of Administration:
Intravenous (IV)

Contraindications:
•Hypokalaemia
•Metabolic alkalosis
•Renal failure with pronounces hypercatabolism, if the uraemic symptoms cannot be corrected with haemofiltration
•Insufficient arterial pressure in the vascular access
•Systemic anticoagulation (high risk of haemorrhage)

Warnings and Precautions:
HEMACOM LF should be mixed before use by mixing solution from Compartment A and B. Use within 24 hours after reconstitution. The haemodynamic status, fluid, electrolyte and acid-base balance should be closely monitored during the CRRT procedure. Before use check for minute leaks by squeezing bag firmly. Discard if leakage is detected. If any solid particle, growth or turbidity appears during storage, the product should not be used. For single use only. Discard unused portion. Not for direct infusion. The administration of CRRT has to be strictly carried out under aseptic condition. The use of contaminated haemofiltration and haemodialysis solution may cause sepsis, shock and death.

Interactions with Other Medicaments:
Some medicament may be incompatible with HEMACOM LF. The compatibility should be checked before use. Generally, other medicament should be administered through different line.
The blood concentration of filterable/dialysable drugs may be reduced during treatment. Corresponding corrective therapy should be instituted if necessary. Interactions with other medications due to electrolyte and/or acid-base imbalances can be avoided by correct dosage of the solution for haemofiltration and haemodialysis and precise monitoring. However, the following interactions are conceivable:
•The risk of digitalis-induced cardiac arrhythmia is increased during hypokalaemia.
•Vitamin D and medicinal products containing calcium, e.g. calcium carbonate as phosphate binder, can increase the risk of hypercalcaemia.
•Additional sodium bicarbonate substitution may increase the risk of metabolic alkalosis.

Statement on Usage during Pregnancy and Lactation:
Pregnancy and Lactation:
There are no adequate data from the use of HEMACOM LF in pregnant or lactating women. The prescriber should consider the benefit/risk relationship before administering HEMACOM LF to pregnant or breast-feeding women.

Adverse Effects/ Undesirable Effects:
Adverse reactions can result from the solution or the CRRT procedure. Improper use can lead to fluid imbalance and disturbances in electrolyte, acid-base and glucose balance.
Some undesirable effects related to the dialysis treatment can occur, such as nausea, vomiting, muscle cramps and hypotension. Electrolytes disturbances may occur. Special attention must be taken for patients with hypokalaemia as this solution is potassium-free.

Overdose and Treatment:
Overdose should not occur if the procedure is carried out correctly and the fluid balance, electrolyte and acid-base balance of the patient are carefully monitored. However, overdose will result in fluid overload in patients with renal failure. Continued application of haemofiltration will remove excess fluid and electrolytes. In case of hyperhydration, the ultrafiltration must be increased and the rate of administration of the solution for haemofiltration reduced. In the case of a severe dehydration it is necessary to cease ultrafiltration and to increase the inflow of solution for haemofiltration appropriately. Overdose could lead to severe consequences, such as congestive heart failure, electrolyte or acid-base disturbances.

Storage Condition Before and After Reconstitution:
Do not store above 30°C

Shelf Life:
2 years from manufacturing date in proper storage condition. The solution should be used within 24 hours after reconstitution. Do not use after expiry.

Dosage Forms and Packaging Available:
5000mL x 1 Double Compartment PP Collapsible Bag per Carton
5000mL x 2 Double Compartment PP Collapsible Bags per Carton

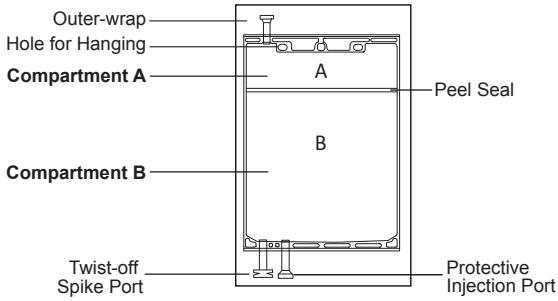
Manufacturer/Product Registration Holder:

AIN MEDICARE SDN. BHD.
Lot 4933, 4934 & PT2464, Jalan 6/44, Kaw. Perindustrian Pengkalan Chepa 2, 16100 Kota Bharu, Kelantan, MALAYSIA.

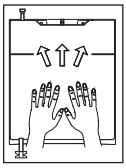
HANDLING INSTRUCTION

AIN MEDICARE CRRT FLUID IN DOUBLE COMPARTMENT COLLAPSIBLE BAG

PARTS OF THE DOUBLE COMPARTMENT PP COLLAPSIBLE BAG

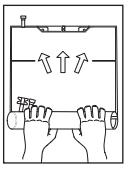


1



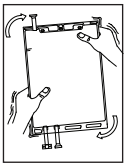
Remove the outerwrap from the bag only immediately before use.
METHOD 1: Break the compartment seal by pressing compartment B with both hands until the two compartments is entirely open

2



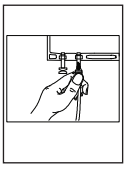
METHOD 2: Using both hands, roll the edge of compartment B towards compartment A until the peel-seal between the two compartments is entirely open.

3



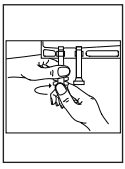
Secure complete mixing of the solution by shaking the bag gently. The solution is now ready for use, and can be hung on the equipment.

4



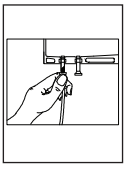
Additives may be injected through injection port.
- Remove the aluminium cap.
- Disinfect the injection port.
- Hold the injection port and inject through the rubber piece.
- Mix thoroughly with the solution.

5



Twist off the tab to expose the spike-port.

6



Insert spike of the administration set into the spike port aseptically.

Date of Revision: 01.08.2019